

REMARKS

Claims 88-98 are pending. Claim 88 has been amended to incorporate the limitations of claims 89, 92 and 93, which have been canceled. Claim 43, which depended from claim 93, has been amended to depend directly from claim 88. No new matter has been added by way of these amendments and support for these amendments can be found in the original claims as filed. Accordingly, entrance of the amendments and consideration of the remarks below is requested.

The Pending Claims are Inventive over Williams, et al.

Claims 88-98 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Williams, et al., (1998) Molecular Microbiology 27(1):171-186 in view of Campbell, Queen, et al. (US Patent No. 5,530,101), and Reiter, et al. (U.S. Patent No. 6,261,791). Applicants traverse this rejection.

The examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, (Fed. Cir. 1993). Only if this burden is met does the burden of coming forward with rebuttal argument or evidence shift to the applicant. *Id.* at 1532. When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988).

To establish a *prima facie* case of obviousness the Office must, *inter alia*, point to some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). The references cited by the Office in support of the present rejection do not establish a *prima facie* case of obviousness because they do not provide the requisite motivation to combine or modify the cited references to achieve the claimed invention.

The Williams, et al. paper was directed to studying proteins involved in bacterial pathogenesis. (See abstract at 171). Williams, et al. did not teach or suggest the generation of a monoclonal antibody nor did it teach or suggest labeling such an antibody with a diagnostic or

therapeutic agent. Monoclonal antibodies are expensive and time consuming to make. Accordingly, for one of ordinary skill in the art to be motivated to make such an antibody, there would have to be some demonstrative advantage for a monoclonal antibody over polyclonal antibodies would have to exist for someone to be motivated to make a monoclonal antibody the sequence disclosed by Williams, et al. The Office has not presented such a motivation, nor does one exist in the cited references.

Similarly, there is no motivation in any of the references cited, nor in the art as a whole, for one of ordinary skill in the art to generate a monoclonal antibody against the claimed protein which has been labeled with a diagnostic or therapeutic agent. As mentioned above, the Williams, et al. reference sought to identify proteins that interacted with *Neisseria gonorrhoeae* opacity-associated (Opa) proteins. The protein Opa interacting proteins (OIPs) identified presumably appear on the surface of normal cells and are associated with *N. gonorrhoeae* infection. As such, there would be no motivation to attach a diagnostic agent to an antibody against the OIP because detecting the protein would say nothing about the health of the cell displaying the protein based on the teachings of Williams, et al. or any of the other cited papers for that matter. Moreover, there would be no motivation to attach a therapeutic marker to an antibody against an OIP in view of the cited art, because Williams, et al. does not teach or suggest that killing cells which express the protein would be effective to treat a *N. gonorrhoeae* infection.

The other references cited by the Office similarly fail to provide a suggestion or motivation to prepare a monoclonal antibody and then label it with a diagnostic or therapeutic agent. As such, the combination of references cited against the pending claims does not constitute a *prima facie* case of obviousness. Therefore, the present rejection should be withdrawn.

CONCLUSION

In view of the above, Applicants submit that the Office has failed to articulate a prima facie case of obviousness. Accordingly, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 511582002800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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